

US EPA ARCHIVE DOCUMENT

DATE OUT: 04/MAY/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
DP BARCODE D#274301 EPA RECEIVED DATE: 16/APR/2001 REG./File Symbol No.: 499-UOA
PRODUCT NAME: Whitmire Micro-Gen TC 234, 0.011% Abamectin MRID No.: 453784-01
COMPANY NAME: Whitmire Micro-Gen Research Laboratories, Inc. ACTION CODES: 161

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

TO: 24 Meredith Laws/Thomas Harris
Insecticide-Rodenticide Branch/RD (7505C)

INTRODUCTION: ~~PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED~~

In a letter dated 10/APR/2001, the applicant responded to EPA's letter of 22/FEB/2001 and re-submitted requesting a FIFRA Section 3(c)(3)(B)(i)(I) "me-too" registration of subject product. In support of this action, the applicant included product chemistry data, revised basic and one alternate formulations CSFs both dated 10/APR/2001, a label EPA received 16/APR/2001, a revised Data Matrix dated 10/APR/2001. In the cover letter, it was apparent that an authorization letter was requested from SC Johnson & Son, Inc. to allow the Agency access to MRIDs #440210-01 & 442359-01 to support the storage stability and corrosion characteristics requirements for subject product.

FINDINGS:

- 1a. The subject product, an insecticide ant bait, is intended for use in residential areas including schools, food handling establishments, supermarkets and other commercial and industrial buildings.
- 1b. The subject product is produced by a non-integrated formulation system, meaning that the technical source in the product is registered. The product contains [REDACTED] (label claim, 0.011 on the CSF?).
2. The submitted/referenced product chemistry data is adequate and support a FIFRA Section 3(c)(3)(B)(I) "me-too" registration of subject product.
3. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of [REDACTED]. The method included with this submission, Method #Tc-234-1, MRID #453784-01, also reviewed in this memorandum, is entitled "HPLC Method of Analysis for Determination of Abamectin Ant Bait Whitmire Research Laboratories Dual Choice Ant Bait."
4. The label claim nominal concentration of [REDACTED] Abamectin is inconsistent with that on the proposed formulations cited at 0.011%. The applicant should be advised to either revise the label ingredient statement or the CSFs. a basic and one alternate formulations CSFs both dated 10/APR/2001, for consistency in achieving the desired nominal concentration for Abamectin.
- 5a. The submitted product's basic and one alternate formulations CSFs both dated 10/APR/2001 were filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2.
- 5b. The upper limits of two inert ingredients were slightly higher than the recommendation of

the standard certified limits in 40CFR§158.175(b)(2). However, adequate explanations were provided by the applicant as per the regulations of 40CFR§158.175(c). All other limits are within the recommendations of 40CFR§158.175(b)(2).

5c. All ingredients claimed on the CSFs are cleared for use in pesticide formulations.

RECOMMENDATIONS:

After resolving Finding 4 above, we will have no objections for a FIFRA Section 3(c)(3)(B)(i)(I) "me-too" registration of subject product.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 10/APR/2001 was included with this submission claiming no confidentiality of any of the submitted on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C).
2. A GLP statement dated 12/APR/2001 was included with this submission to the effect that the submitted studies were not within the scope of the GLP requirements of 40CFR§160. Others were referenced and the applicant has no knowledge if they were conducted in compliance with the GLP requirements.

DATA SUBMITTED

MRID #453784-01 The submitted study entitled: "Whitmire Micro-Gen TC 234 - Product Chemistry Data Requirements & Results Summary. The studies were compiled by Dana M. Thomas; Performed by Whitmire Micro-Gen Research Laboratories, Inc. of St. Louis, Missouri; Completed on 10/APR/2001 (8 pages).

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The subject product, Whitmire Micro-Gen TC 234, [REDACTED]
[REDACTED] plus cleared inert ingredients (refer to product's CSF dated 10/APR/2001).

830-1600 Description of Materials Used to Produce the Product:

Refer to Confidential appendix A.

830-1650 Description of Formulation Process:

Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:

Refer to Confidential appendix A.

830-1700 Preliminary Analysis:

Refer to Confidential appendix A.

830-1750 Certified Limits:

Refer to Confidential appendix A.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

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830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of [REDACTED]

The method included with this submission, Method # Tc-234-1, MRID #453784-01, is entitled "HPLC Method of Analysis for Determination of Abamectin Ant Bait Whitmire Research Laboratories Dual Choice Ant Bait." The method uses dibutylphthalate as an internal standard for the determination of abamectin. The HPLC used was Perkin Elmer Analyst HPLC System, Perkin Elmer LC-235 Diode Array Detector. Uses C18, 5 μ column (150 x 4.5 mm). The column temperature was 45°C at a flow rates of 1.5 ml/min water or methanol & the injector volume was 50 μ l at wave length of 255 nm. Sample calculation was included with this submission.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GUIDELINE REFERENCE NO.(GRN830.)/TITLE	VALUE OR QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES
.6302 Color	Straw colored.
.6303 Physical State	Solid.
.6304 Odor	Mild, grain-like.
.6314 Oxidation/Reduction: Incompatibility	Does not contain oxidizing or reducing agents.
.6315 Flammability/Flame Extension	NA
.6316 Explodability	Not potentially explosive.
.6317 Storage Stability	Stable for a period of one year.
.6319 Miscibility	NA
.6320 Corrosion Characteristics	Non corrosive.
.6321 Dielectric Breakdown Voltage	NA
.7000 pH	NA
.7100 Viscosity	Refer to MRID #442359-01.
.7300 Density/Relative	0.96 g/cm ³

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Product Chemistry Review For 453784-01

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

Identity of product inert ingredients.

_____ Identity of product inert impurities.

☒ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s)

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
